partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

15. The Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), is a Delaware Corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. At all times material hereto, this Defendant was in the business of manufacturing, assembling, developing and/or supplying the pharmaceutical known as Redux. On or about November 21, 1995, Defendant, Boehringer, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Interneuron, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendants, Interneuron and Wyeth Defendants, including supplying Defendants Interneuron and the Wyeth Defendants, with all of its requirements of Redux for sale in the United States. At all times material hereto, Boehringer does and did business in Massachusetts and manufactured, developed, tested, assembled, packaged, labeled, prepared and/or supplied Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs. Upon information and belief, the Redux ingested by Plaintiffs was

manufactured, developed, tested, assembled, packaged, labeled, prepare and/or supplied by Boehringer. Though "Diet Drugs" as provided herein shall otherwise include both Redux and Pondimin, all allegations referencing "Diet Drugs" as set forth herein relating to Boehringer shall only relate to Redux.

Factual Background

16. Aminorex, discovered in 1960 by United States pharmaceutical company, McNeil Laboratories, was a drug from the same family of drugs as fenfluramine and dexfenfluramine. Aminorex was touted as a wonder weight loss drug which, like fenfluramine and dexfenfluramine, worked by increasing brain serotonin while inhibiting reuptake of serotonin.

17. Fenfluramine is made up of two "mirror image" halves or isomers: dexfenfluramine (right-handed isomer or d-isomer), the isomer which increases the release and prevents the reuptake of serotonin in the brain, thereby presumably reducing appetite, and levofenfluramine (left-handed isomer or l-isomer), which increases dopamine release but can cause the unwanted side-effect of drowsiness.

18. In 1963, Science Union & Co., an affiliate of Servier, entered into a licensing agreement with Wyeth Defendants' predecessor, A.H. Robins, giving it the right to market, promote, distribute, detail, sell or otherwise profit from the sale of fenfluramine in the United States.

19. In 1965, after securing authorization for the marketing of fenfluramine in Europe, Servier commenced the sale of products containing fenfluramine in Europe. This same year, Aminorex was introduced into the European market.

20. However, by 1967, evidence began to surface that the ingestion of Aminorex was associated with pulmonary hypertension. Over the next five years, Aminorex caused in Europe a

ten-fold increase in pulmonary hypertension cases, permanent injury to patients who suffered significant oxygen deprivation, and numerous deaths. In light of the reports of Aminorex induced pulmonary hypertension, McNeil Laboratories prudently suspended its research and efforts to bring Aminorex to the United States market. By 1972, Aminorex was removed from the European market.

21. In or about 1970, during the European experience, Dr. Richard Wurtman, a faculty member of the Massachusetts Institute of Technology (MIT) and the founder of Interneuron secured a United States patent for use of fenfluramine as a diet drug. Like Aminorex, Fenfluramine was touted as a wonder weight loss drug designed to effect weight loss by increasing brain serotonin while inhibiting reuptake of serotonin. The patent and rights to market fenfluramine as an obesity drug were thereafter sub-licensed by Dr. Wurtman and/or MIT to Servier.

22. Despite the European experience, in June of 1973, fenfluramine was introduced into the United States market by A.H. Robins which sold fenfluramine under the brand name Pondimin. However, after introduction into the United States market, sales of fenfluramine languished both because of restrictions in prescribing under the Controlled Substance Act and because the fenfluramine isomer levofenfluramine caused users to become lethargic and tired when using Pondimin alone.

23. In 1977, Finnish researchers found a causal link between fenfluramine/ dexfenfluramine and heart valve lesions. Based on a study of weight-loss drugs including Aminorex and fenfluramine/dexfenfluramine and their effects on the release of serotonin, it was discovered that not only was the concentration of free serotonin in the blood vessels of the lungs caused by the weight-loss drug responsible for pulmonary hypertension, but also that the vessel

wall-thickening mechanism which caused pulmonary hypertension was likely the identical mechanism which caused right-sided heart valve thickening and regurgitation in carcinoid patients.

24. Recognizing the problems in selling fenfluramine caused by the levofenfluramine isomer which caused users to become lethargic and tired, in or about 1980, Servier discovered a commercially feasible way to chemically isolate and separate the active ingredient in fenfluramine, being the right-sided d-isomer (dexfenfluramine) from the undesirable left-sided isomer (levofenfluramine) and commissioned and/or contracted Dr. Wurtman and/or MIT to further research, formulate, test, develop, design, license, assemble, compound, manufacture, market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux for the United States market. This same year, MIT and/or Dr. Wurtman, secured a United States patent for use of dexfenfluramine as an obesity drug and thereafter, as with fenfluramine a decade earlier, sub-licensed the patent back to Servier.

25. On October 3, 1981, Dr. J.G. Douglas published *Pulmonary Hypertension and Fenfluramine* in the British Medical Journal. On January 25, 1986 an article entitled *Irreversible Pulmonary Hypertension after Treatment with Fenfluramine*, was published in the British Medical Journal. Defendants knew, or should have known, of the British Medical Journal articles and how those articles related to fenfluramine and dexfenfluramine, and their propensity to cause valvular heart disease, and secondary pulmonary hypertension.

26. While the sales of Pondimin languished between 1973 and 1984, sales of Pondimin increased, however, after several studies or reports sponsored, subsidized, and/or supported by the Wyeth Defendants' predecessor, A.H. Robins, were published within the medical community. Specifically, in 1984, Dr. Michael Weintraub published *A Double-Blind Clinical*

Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination in the Archives of Internal Medicine. Dr. Weintraub's study was sponsored, subsidized, and/or supported by A.H. Robins (later acquired by the Wyeth Defendants). Despite noting some adverse effects associated with fenfluramine, Dr. Weintraub failed to examine the long-term safety of fenfluramine. Instead, the study focused on the short-term effectiveness of the drugs used individually, and in combination with phentermine.

27. In 1985, after securing authorization for the marketing of dexfenfluramine in Europe, Servier commenced the sale of products containing dexfenfluramine in Europe under the brand/trade names Adifax (in England) and Isomeride (in France).

28. In or about 1989, after MIT and Dr. Wurtman had researched, formulated, tested, developed, designed, licensed, assembled and compounded dexfenfluramine for several years in preparation for submitting dexfenfluramine for FDA approval and licensing for sale in the United States, Dr. Wurtman incorporated Defendant, Interneuron.

29. In or about 1990, Servier sub-licensed the rights to market, promote, distribute, detail, sell or otherwise profit from the sale of dexfenfluramine in the United States back to Interneuron.

30. On or about February 27, 1990, representatives from Interneuron, Wyeth Defendants and Servier convened to discuss "certain situations pertaining to Pondimin", including protocols and respective responsibilities relating to adverse event reporting and safety information, during which Servier representatives Madame Derome-Tremblay and Christine Bazantay advised the Wyeth Defendants that there was a need to update the 1972 labeling for Pondimin. However, there was no change in the labeling of Pondimin between 1990 and mid-1996.

31. In September of 1990, Servier, co-licensor of both Pondimin and Redux in coordination with Interneuron and the Wyeth Defendants, completed a study regarding the

effects of fenfluramine isomers on Fisher Rats which showed significant levels of focal fibrosis in the hearts of rats treated with doses of dexfenfluramine as compared with hearts of untreated rats. Defendants knew or should have known of the Fisher Rat study and how those articles related to fenfluramine and dexfenfluramine. At the very least, Interneuron and the Wyeth Defendants knew or should have known of the results of the Fisher Rat study by March 19, 1992, the date that the study was released by Servier.

32. On March 18, 1991, Interneuron, filed a petition with the DEA requesting that fenfluramine and its isomer dexfenfluramine be removed from Schedule IV and all other controls of the Controlled Substances Act (CSA) such that, among other things, both Pondimin and Redux could be dispensed and prescribed in larger quantities and over longer incremental dosage durations. Interneuron's efforts to gain the de-scheduling of both fenfluramine and dexfenfluramine, continued by using politicians and large anti-regulatory political action committees aimed at persuading both the DEA and FDA.

33. On or about October 25, 1991, Interneuron, through the assistance of Cato Research, Ltd. filed an Investigational New Drug Application with the FDA in furtherance of securing approval for Redux.

34. In 1992, Dr. Weintraub again published a series of articles sponsored, subsidized, and/or supported by the Wyeth Defendants in Clinical Pharmacological Therapies, in which he reported his research regarding the long term use of fenfluramine and phentermine for weight control. Dr. Weintraub's research assumed the safety of fenfluramine, and did not examine the short-term or long-term safety of the drug. The Wyeth Defendants failed to conduct or fund any studies or research regarding the long-term safety of the fenfluramine. The Wyeth Defendants, and later Interneuron, through their sales representative force, promoted Dr. Weintraub's

conclusion that long term combination use of fenfluramine and phentermine was effective for the management of obesity to both physicians, and the public. As a result, sales of Pondimin began to increase dramatically.

35. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid, a predecessor company to the Wyeth Defendants, and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux.

36. On or about April 15, 1993, Interneuron and Wyeth Defendants, through their employees, agents and/or representative parties, including Dr. Bobby W. Sandage, Jr., Interneuron's Vice-President of Research and Development and employees Dukart, Hammershaimb, Gantt, Lefkowitz, Stout and Quinn of Wyeth Defendants, met with Dr. Stuart Rich, Section of Cardiology at University of Illinois at Chicago, an expert in the area of pulmonary hypertension ("PH"), to discuss the cases of PH reported following the use of Redux and "to help put this information into perspective." Interneuron and Wyeth Defendants at this time recognized Dr. Rich as a Principal Investigator and member of the steering committee for the NIH Registry for the Characterization of PH who had reviewed approximately thirty-six (36) cases of the drug relationship between Redux and PH and further admitted that there was an association between PH and the intake of certain exogenous substances such as and including Redux. Dr. Rich advised Interneuron and Wyeth Defendants that there was an increased risk for PH which necessitated caution until more definitive information was available. This information placed or should have placed the Defendants on notice of the association between the Diet Drugs and pulmonary hypertension, and that pulmonary hypertension may be related to valvular heart disease.

37. By 1993, the Wyeth Defendants labeling for Pondimin indicated that there were only 4 reported cases of pulmonary hypertension reported in association with the drug. Yet, that same year, Dr. Francois Brenot published an article related to the association of Fenfluramine and pulmonary hypertension, in the British Heart Journal. Dr. Brenot identified 25 cases of pulmonary hypertension associated with the use of fenfluramine and/or dexfenfluramine. The Wyeth Defendants knew or should have known of the Brenot article. The Wyeth Defendants should have known by at least 1993 that Pondimin was defective and unreasonably dangerous and further that its Pondimin labeling was false.

38. On or about May 21, 1993, Interneuron filed its NDA with the FDA for the approval of Redux. In its bid for FDA's Redux approval, Interneuron and Wyeth Defendants relied upon several pivotal "studies" in its NDA, including but not limited to, the Noble Study, the Van Itallie Study, and the Index Study.

39. Interneuron and Wyeth Defendants knew at the time of submitted the NDA for Redux to the FDA that these pivotal studies where flawed, defective and substandard, thereby effecting misrepresentations to the FDA, the medical community, Plaintiffs' prescribing physicians and Plaintiffs. In particular, Interneuron and Wyeth Defendants were on notice through advice by Interneuron's own auditor, Bruce Sturgeon (such internal audits being typically required and expected of NDA applicants), both before and during the NDA submission and subsequent supportive documentation, that:

a. the Noble Study had careless record keeping, several protocol violations, a lack of documentation for final disposition of the drug and missing progress reports to the IRB;
b. the Van Itallie Study, which Mr. Sturgeon concluded would probably not be accepted by the FDA – though Interneuron still included the same in its NDA — included a protocol change increasing the allowable weight fluctuation from 3 kilograms to 7.5 percent of body weight without notifying the IRB or

FDA, thereby reflecting a gross deviation from good clinical practices; used three patients who did not meet the revised criteria for the study; and contained inaccurate drug accountability for all patients, exacerbated by the fact that the drug was a controlled substance; and

c. the Index Study was poorly monitored, lacked proper and complete documentation, contained high error incidents in key data reporting found across all sites, and suffered from poor data quality consistent among all sampled sites which could be extrapolated to all sites in the Index Study.

40. During the time Interneuron filed its NDA for Redux, Interneuron and Wyeth Defendants knew or should have known that there were serious health risks associated with Redux which were neither sufficiently nor adequately expressed in either its NDA or its 120 Day Update.

41. By 1993, nearly two decades after the 1977 Finnish study, numerous medical reports and studies had been published within mainstream medical journals and publications firmly establishing the same causal connection between high concentrations of free circulating serotonin, as caused by fenfluramine and dexfenfluramine, and heart valve lesions, including but not limited to: Ann Redfield MM, Nicholson WJ, Edwards WD, Tajik AJ. *Valve disease associated with ergot alkaloid use: echocardiographic and pathologic correlations*. Ann Intern Med 1992;117:50-52; and Pellikka PA, Tajik AJ, Khandheria BK, et al. *Carcinoid heart disease: clinical and echocardiographic spectrum in 74 patients*. Circulation 1993;87:1188-96. As reaffirmed by these medical journal publications and their long and numerous progeny spanning nearly three decades, there was an available body of scientific knowledge identifying the pharmacologic affects of various anorexic agents, including fenfluramine and dexfenfluramine, on circulating (release, reuptake inhibition and monoamine oxidase inhibition) serotonin. Moreover, there was an available body of scientific knowledge relating elevations in serotonin as found in ergotamine toxicity and carcinoid syndrome, like fenfluramine and

dexfenfluramine, to incidents of VHD. During this period of time in which Interneuron and the Wyeth Defendants were proceeding with the Redux NDA and while the Wyeth Defendants continued to sell Pondimin on the United States market, Interneuron and Wyeth Defendants knew or should have known that fenfluramine and dexfenfluramine caused an increase in circulating serotonin and that a serotonin-related mechanism was directly associated with VHD. Interneuron and Wyeth Defendants failed to disclose the connection between the Diet Drugs and VHD and/or failed to perform pre-marketing studies and post-marketing surveillance which would have detected this fact.

42. In or about 1994, cases of heart valve damage from the use of the Diet Drugs began to appear throughout the Country including sonographer, Pamela Ruff's discovery in Fargo, North Dakota of VHD in patients who had ingested Pondimin. Numerous cases of Diet Drug induced VHD prompted physicians at the Mayo Clinic to undertake a case review which ultimately resulted in the untimely forced withdrawal of the Diet Drugs from the market.

43. In February 1994, the preliminary results of the International Primary Pulmonary Hypertension study ("IPPH Study") entitled "Appetite Suppressants and the Risk of Primary Pulmonary Hypertension" was released and available to the Defendants. The preliminary results of the IPPH Study confirmed the association between fenfluramine and dexfenfluramine and pulmonary hypertension. The Defendants failed to reveal the number of cases of pulmonary hypertension associated with the Diet Drugs to the public, Plaintiffs, or Plaintiffs' prescribing physicians.

44. In March and April of 1994, Wyeth Defendants received 10 reports relating to VHD in the consumer public a result of the use of Pondimin, which indicated or should have indicated a

clear signal to Wyeth and their partners including Interneuron of the association between the Diet Drugs and VHD.

45. On or about March 23, 1994, Dr. Sandage and Lisa Stockbridge of the FDA discussed the pending NDA for Redux, at which time Dr. Stockbridge and Dr. Sandage of Interneuron discussed the concerns about the pulmonary hypertension issue and that the concerns might have been strong enough to consider withdrawing the NDA.

46. On June 24, 1994, the Wyeth Defendants' Safety Surveillance Monitor, Amy Myers, wrote a memo to Wyeth Defendants' Medical Monitor, Fred Wilson, and indicated that the Wyeth Defendant's database contained 37 cases of pulmonary hypertension associated with Pondimin.

47. After a hostile bid to acquire American Cyanamid commenced in mid-1994, American Home Products Corporation completed its acquisition of American Cyanamid in November of 1994, acquiring its assets and liabilities, and securing its rights to the sublicense agreement between Interneuron, American Cyanamid and Servier.

48. By October 10, 1994, Wyeth Defendants, through its leadership, Hans Mueller and Fred Hassan, agreed to pay Interneuron $8 million dollars, representing American Cyanamid's equity investment in Interneuron and its dexfenfluramine licensing fees, to obtain Interneuron's approval for Wyeth Defendants having more direct participation in Redux, thereby commencing a new phase of both the joint venture between Interneuron and Wyeth Defendants and their combined relationship with Servier.

49. Interneuron had advised the FDA that withdrawal of the NDA from a financial standpoint was out of the question because the company would be ruined and, further, asked that continuing consideration and courtesies be extended Interneuron in its Redux application.

50. By October of 1994, Interneuron and Wyeth Defendants learned that there were many problems concerning the FDA's approval of Redux including that: (a) that secondary pulmonary hypertension was an adverse effect in patients treated with Redux; and (b) that the risk/benefit ratio of Redux was "unsatisfactory". Further, the FDA had indicated it had found Redux "unapprovable." However, at the request of Interneuron, the FDA agreed to withhold sending an unapprovable letter until April of 1995.

51. On or about January 5, 1995, Wyeth Defendants received further information on VHD among Pondimin users in the form of follow-up reports to those originally reported in 1994 as well as 6 new reports of VHD among Pondimin users. In the months of January, February, July and August of 1995 and thereafter, Wyeth Defendants received additional new reports of Diet Drug induced VHD, however, Wyeth Defendants failed to obtain any more information about these reports from any source; made no attempt to have the reports evaluated by any cardiologists; failed to undertake further testing or analysis of any sort; and made no attempt to look back through its computer database to look for other reports of VHD. Furthermore, Wyeth Defendants mislabeled VHD adverse events as "non-serious" and did not report many of these VHD adverse events to the FDA and refused to undertake any measures to ensure its Pondimin label included VHD as a possible adverse event.

52. On or about February 17, 1995, the FDA's Dr. Bilstad advised Interneuron's Dr. Sandage that the Redux NDA was nonapprovable and that the principal reason was because "the application did not contain adequate safety data to define the risk of developing pulmonary hypertension."

53. On June 15, 1995, the Wyeth Defendants' James Ottinger reported to Joseph Bathish the status of the European Committee on Proprietary Medicinal Product's ("CPMP")

pharmacovigilance discussion wherein the CPMP working party concluded that a causal relationship between anorectic agents, like fenfluramine and dexfenfluramine, and the occurrence of pulmonary hypertension had been established.

54. On or about July 19, 1995, Interneuron, in its bid to have Redux approved, concluded that significant public relations and lobbying were needed as stated by Interneuron's Dr. Sandage: "[w]e agree that a significant PR/lobbying is needed. We will be getting numerous parties involved immediately. This includes the Washington, D.C. PR firm of Hill and Knowlton, possibly former US Surgeon General C. Everett Kroop, M.D., Nancy Taylor, and Yur Strobos, M.D., Ph.D. (for high level contacts at the FDA and Congress) Judy Stern, Ph.D. and Dick Atkinson (for working through American Obesity Association). We intend to add additional groups as necessary."

55. By 1995, additional medical reports and studies had been published further elevating the pre-existing scientific knowledge within the medical community that increases in serotonin caused VHD. These reports and studies, including Robolio PA, Rigolin VH, Wilson JS, et al. *Carcinoid heart disease: correlation of high serotonin levels with valvular abnormalities detected by cardiac catheterization and echocardiography*. Circ 1995;92:790-5, published on or about August 15, 1995 set forth a clear warning to all within the medical community including Defendants that serotonin releasing agents such as fenfluramine and dexfenfluramine cause VHD.

56. In September of 1995, JoAnn Manson, along with several of her colleagues at the Harvard Medical School, issued a press release regarding the results of a "study" of the health risks associated with obesity claiming that the data the authors had collected from the Nurses Health Study provided compelling evidence for the proposition that "even mild to moderate

overweight is associated with a substantial increase of premature death." In October of 1995, Dr. Manson testified before the FDA that this study supported the conclusion that the FDA should approve dexfenfluramine, though it later became evident that this fatally flawed and erroneous "study" found no statistically significant increased risk of mortality associated with mild to moderate obesity. Dr. Manson later revealed that she in fact was a paid consultant to Interneuron.

57. On or about September 15, 1995, Interneuron decided that it would secure the services of General Alexander M. Haig, Jr. to attend upcoming FDA meetings on Redux in an effort to exert pressure and influence aimed at the approval of Redux. Alexander Haig was hired by Interneuron and became Interneuron's Director.

58. In or about October, 1995, during the time Interneuron was continuing discussions with the FDA, Interneuron also attempted to secure the services of Newt Gingrich to exert influence upon the FDA.

59. On or about October 2, 1995, Dr. Rich advised Interneuron it was clear that evidence of safety for long-term use was lacking with respect to pulmonary hypertension. Dr. Rich advised Interneuron regarding the IPPHS data which showed the risk of significant injury being at least one in 10,000 users or 100 cases per million per year and questioned Interneuron as to the clinical safety of Redux based on Interneuron's own claims that Redux would cause weight reductions between 5% and 15%, which would translate into 248 lives saved per million per year. Further, Dr. Rich questioned the efficacy of Redux assuming Redux produced a consistent average 5% reduction in body weight stating, "[a]s I compute the 5% weight loss in a 300lb individual to a new weight of 285lbs, I question as to whether that will truly translate in substantial improvement in health to the patient." Dr. Rich further advised that the Redux label needed to

clearly indicate to the prescribing physician that there is a causal relationship between Redux and the development of PH. However, the Integrated Summary of Safety for Redux as set forth in it label, without a Black Box Warning, ultimately stated that:

> Anecdotal cases of PH have been associated with other weight loss agents such as phentermine and the racemic d,l-fenfluramine. In Europe, in post-marketing surveillance between 8/84 and 7/93 there were reports of PH in 51 patients being treated with dexfenfluramine

60. On or about October 12, 1995, Interneuron had further discussions with the FDA's Dr. Lutwak who confirmed the FDA's continued concerns about the safety of Redux which had proven to have resulted already in too many adverse event reports.

61. In or about November of 1995, Interneuron again attempted to push its lobbying efforts and caused to be issued a letter to Speaker Newt Gingrich stating: "This letter voices my deep concern about certain actions of the FDA. Our friends at the FDA are doing it again - I have used Pondimin for 22 years as a safe alternative to more stimulating drugs for obesity. I have never had any problems with it. An improved form, dexfen, has the same effect but without the drowsiness of the parent compound. It has been in general use since 1985 in Europe. The FDA has again denied our citizens an effective treatment of a potentially fatal disease (obesity)."

62. At a meeting of an FDA advisory committee on Redux, Interneuron solicited the services of Director Alexander Haig, who on behalf of Interneuron provided incorrect and unsubstantiated information to the FDA including representations that Redux helps twice as many people lose 10 percent of their weight as a placebo in preliminary tests and that ten million people have used the drug internationally without side effects.

63. On or about November 21, 1995, Defendant, Interneuron, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Boehringer, by which Boehringer agreed

to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendant, Interneuron, including supplying Defendant, Interneuron, with all of its requirements of Redux for ultimate sale in the United States including the State of Massachusetts, and the states where Plaintiffs ingested the Diet Drugs.

64. On or about January 18, 1996, the FDA advised Interneuron's Dr. Sandage that further changes to the labeling for Redux were recommended pursuant to the review of Dr. Lutwak despite the fact that the FDA Advisory Committee had voted at a second meeting to approve Redux, albeit without the benefit of the safety information which Interneuron and the Wyeth Defendants had in their possession.

65. On or about April 29, 1996, the FDA approved Redux for sale in the United States and the first sales of Redux on the market in the United States began in June of 1996.

66. On or about July 17, 1996, after approval of Redux by the FDA, the FDA's Randy Hedin contacted Interneuron's Sonja Loar and reiterated again the FDA's ongoing concerns regarding pulmonary hypertension and the FDA's consideration of a Black Box Warning to which Interneuron voiced opposition in favor of continuing with the proposed bold-face, all CAPS warning.

67. On or about August 19, 1996 the FDA met with Interneuron and stated that it still felt a Black Box Warning may be appropriate for Redux, a fact that Interneuron later acknowledged given the serious and high risk of pulmonary hypertension associated with Redux.

68. On or about, August 26, 1996, the New England Journal of Medicine reported the final results of IPPH Study which had been preliminarily released in February 1994. The IPPH Study concluded that fenfluramine-based anorexigens, such as fenfluramine and dexfenfluramine, increased the risk of PH .

69. On or about August 29, 1996, an article was published in the New England Journal of Medicine authored by Dr. Stuart Rich and other preeminent doctors entitled *Appetite-suppressant Drug and the Risk of Primary Pulmonary Hypertension*" which addressed the results of the IPPH study and concluded that that the use of fenfluramine/dexfenfluramine substantially increased the risk of pulmonary hypertension in that the risk associated with dexfenfluramine use was equal to 14 deaths caused by per million patients treated thereby yielding a very "problematic" benefit:risk ratio of 20:1 or 280 lives saved for 14 deaths caused.

70. Defendants were aware of the result of the IPPH study by at least November 1995, well in advance of its official publication in the New England Journal of Medicine, nevertheless, Defendants failed to apprise the public or physicians that the risk of contracting PH was many multiples of that previously reported by the Wyeth Defendants in their label and other literature. Even after the Brenot article and the preliminary release of the IPPH Study, Interneuron and the Wyeth Defendants failed to withdraw the New Drug Application ("NDA") for Redux and the Wyeth Defendants failed to remove Pondimin from the market when Interneuron and Wyeth Defendants knew of the extreme danger, causal relationship and substantial risk of harm associated with the use the Diet Drugs.

71. Even prior to their knowledge of the IPPH Study, the manufacturers and distributors of the Diet Drugs knew about the risks of PH associated with using the subject drugs from experience with and subsequent banning of such drugs in various countries in Europe as described herein above. Defendants did not apprise Plaintiffs, the public at large, or Plaintiffs' physicians of these material facts and risks.

72. Between 1994 and 1996, while fenfluramine was on the United States market and while dexfenfluramine was under FDA consideration, at least 30 cases of heart valve problems

were identified among users of the Diet Drugs examined by physicians in Belgium. This information was reported to Belgian drug regulators and Servier. Servier's partners and or licensees, including Interneuron and the Wyeth Defendants, knew or should have known of the numerous reports of VHD among Diet Drug users.

73. Interneuron and Wyeth Defendants failed to properly investigate the reports and failed to warn doctors and consumers, including Plaintiffs, regarding the known risks of VHD associated with use of the Diet Drugs. Interneuron and Wyeth Defendants also did not adequately inform the FDA regarding the Belgian studies by suggesting that the reports were irrelevant because some of the studied individuals had also ingested herbs which Interneuron and Wyeth Defendants allegedly assumed caused VHD. In fact, Wyeth Defendants and Interneuron only reported one Belgian case to the FDA involving Redux's ingredient dexfenfluramine in an amendment to its Redux NDA.

74. During the time fenfluramine was sold on the United States market and at the time Interneuron filed its New Drug Application with the FDA for dexfenfluramine, Defendants had available to it the information that its European counterpart sub-licensee Servier had accumulated during its marketing of dexfenfluramine in Europe for over a decade concerning the safety and efficacy of the dexfenfluramine, including medical literature, adverse event reports relating to the use of the dexfenfluramine in Europe, clinical and other medical studies, and communications from medical providers. This information which was known or should have been known by Interneuron and Wyeth Defendants established inter alia, that:

a. by 1977, Defendants knew or should have known that the mechanism of action of the Diet Drugs and their affects on serotonin were responsible for causing pulmonary hypertension in exposed patients, and knew or should have known that the same mechanism of action also was likely the same mechanism which caused heart valve disease in carcinoid patients;

b. by 1992, Defendants knew or should have known that the Diet Drugs had been associated with fibrotic changes in the heart tissues of animals exposed to the drug;

c. by February of 1994, Belgian physician Mariane Ewalenko, MD advised Servier of seven patients who had been taking the Diet Drugs and who were found suffering from valvulopathy;

d. between 1994 and 1996, other Belgian physicians, including Jean Malak, MD and Jean-Francois Adam, MD, discussed and corresponded extensively with Servier officials regarding numerous cases involving valvular regurgitation suffered by patients who had ingested the Diet Drugs;

e. between 1994 and 1996, various Belgian doctors reported at least 30 cases of VHD associated with the use of the Diet Drugs;

f. between 1994 and 1996, numerous adverse event reports were received by Interneuron and Wyeth Defendants which provided or should have provided notice of the association between ingestion of the Diet Drugs and VHD; and

g. by 1995, available and reliable medical literature was available to Defendants from which Defendants' either knew or should have known that Diet Drugs caused an increase in circulating serotonin and that this very serotonin-related mechanism, also found in ergotamine toxicity and carcinoid syndrome, created a high risk for VHD.

75. On April 2, 1996, just three weeks before Redux was approved for marketing in the United States, Dr. B. Taylor Thompson, of Massachusetts General Hospital and Harvard Medical School provided an analysis of 32 pulmonary hypertension cases, which were part of the November 1995 Safety Update, to the FDA and to Interneuron and Wyeth Defendants. The Thompson analysis concluded that of the 32 cases, sixteen (16) cases involved secondary pulmonary hypertension. Dr. Thompson specifically placed Interneuron and Wyeth Defendants on notice that VHD was one of the primary causes for the secondary hypertension. Interneuron and Wyeth Defendants did not update the November 1995 Safety Update, which would have put the public, the FDA, and plaintiffs' physicians on notice of the relationship between Diet Drugs and VHD.

76. On April 29, 1996, the Defendants introduced the defective product Redux into the United States without informing the public, or Plaintiffs' physicians of the dangers and risks of VHD and secondary pulmonary hypertension associated with the Diet Drugs.

77. On or about June 1, 1996, Interneuron entered into a "Co-promotion Agreement" with the Wyeth Defendants which both reaffirmed the joint venture or partnership between Interneuron and the Wyeth Defendants and provided for Interneuron to market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux in consideration for the payments from Interneuron's co-promoter, Wyeth Defendants, for percentages of profit derived from sales generated by Interneuron's sales representative sales force.

78. On or about August 28, 1996, only four months after approval of Redux, Interneuron and Wyeth Defendants were provided and reviewed a study entitled "Cardiac Adverse Effects of Fenfluramine Isomers" prepared by Dr. Francis Wagniart of Servier revealing a higher incidence among Redux users of PH than was previously known. The findings further established Interneuron and Wyeth Defendants' knowledge of serious adverse side effects caused by the ingestion of the Diet Drugs. However, Interneuron and Wyeth Defendants failed to act responsibly in taking necessary action to protect the public, including Plaintiffs, from Diet Drug related injuries.

79. In March 1997, the Defendants were informed by doctors of heart valve problems among users of the Diet Drugs when they received a detailed report from physicians in meetings at the Mayo Clinic in Rochester, Minnesota. However, Defendants failed to undertake any action to warn or otherwise prevent further injury to the consuming public including Plaintiffs.

80. In July of 1997, the Mayo Clinic discovered additional cases of damage to heart valves caused by the Diet Drugs and made this additional information known to Defendants.

81. On or about July 8, 1997, the Mayo Clinic in Rochester, Minnesota released an emergency report linking the use of the Diet Drugs to unusual, potentially life-threatening disease related to heart valves.

82. Independent medical center data from the Mayo Clinic and elsewhere indicated that the Diet Drugs were associated with heart valve defects in as many as one-third of the patients who used the drug. The Mayo Clinic study concluded that dexfenfluramine users needed to be informed about the risk of PH and VHD.

83. Notwithstanding the fact that Interneuron and the Wyeth Defendants received detailed reports during separate meetings with investigators from the Mayo Clinic and the MeritCare Medical Center in Fargo, North Dakota regarding these findings as early as March of 1997, four months before the *New England Journal of Medicine* article reporting these findings was published, Interneuron and the Wyeth Defendants did not halt the wide spread use of the Diet Drugs until September of 1997.

84. On July 8, 1997, the FDA issued a public health advisory regarding the use of the Diet Drugs which stopped the implementation of the DEA's administrative action relating to de-scheduling.

85. On or about September 15, 1997, the FDA forced Defendants to withdraw the Diet Drugs from the United States market because the independent medical center data from the Mayo Clinic in Rochester, Minnesota, and elsewhere indicated that the Diet Drugs were associated with heart valve defects in as many as one-third of the patients who took the Diet Drugs alone or in combination with phentermine ("the initial Mayo study"). In fact, of 291 patients tested, one-third of them had damaged aortic or mitral heart valves; less than 1 percent of the general population has such damage.

86. On November 11, 1997, results of a study funded by the National Institute of Health ("NIH"), of the association between heart valve abnormalities and the use of the Diet Drugs, individually or in combination with phentermine, were reported at the annual conference of the North America Association for the Study of Obesity in Cancun, Mexico. The study, conducted by investigators at the Hennepin County Medical Center in Minneapolis, Minnesota ("the Hennepin study"), found significant heart valve leaks in 24% of 226 individuals taking one or more of these drugs.

87. Notably, the Hennepin study included a control or comparison group of 81 people matched by age, sex, height, and weight to the 226 cases. The 226 cases took fenfluramine and/or dexfenfluramine, while the 81 controls did not. Only 1% of the controls had significant heart valve leaks. All 307 individuals in the Hennepin study (cases and controls) had echocardiograms, which were read by physicians who were "blind" as to the status of each individual, i.e., the reading physicians had no knowledge as to whether the person had taken the diet drugs or not. The Hennepin study investigators found that dexfenfluramine ("Redux") is as likely to lead to heart valve defects as fenfluramine. Of the 226 patients observed in the Hennepin study, 145 had taken the combination of fenfluramine and phentermine, 40 had taken dexfenfluramine, 27 had taken dexfenfluramine in combination with phentermine, and 14 had taken all three drugs.

88. On November 13, 1997, officials from the FDA, NIH and the Centers for Disease Control issued a joint recommendation for medical monitoring of users of the Diet Drugs.

General Allegations

89. At all times material hereto, Defendants researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold pharmaceutical Diet Drugs which were defective and unreasonably dangerous to consumers, including Plaintiffs.

90. Defendants knew or should have known that the Diet Drugs, when used alone or in combination with phentermine, created significant risks of serious injuries or disorders, including VHD, secondary pulmonary hypertension, related cardiopulmonary dysfunction, cardiomyopathy, congestive heart failure, and/or death, as to which Defendants failed to make proper, reasonable or adequate warning to the public about the risks associated with the use of their products.

91. At all times material hereto, though Defendants knew or should have known that dangerous risks were associated with the use of the Diet Drugs, Defendants proceeded to or permitted the Diet Drugs to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious side effects and dangerous risks.

92. Both during the initial submission of the Redux NDA and thereafter, Interneuron and the Wyeth Defendants did not adequately report to the FDA, the public, and Plaintiffs' physicians information in its possession which related directly the risk of developing valvular heart valve disease and pulmonary hypertension. The public, the FDA, the medical community and Plaintiffs, were misled by these actions and omissions, resulting in Plaintiffs having received no or inadequate warnings regarding the true risks associated with ingesting Redux.

93. Interneuron and Wyeth Defendants failed to conduct sufficient and adequate pre-marketing research and testing to properly determine the risks and severity of serious side effects

including VHD and/or pulmonary hypertension caused by the ingestion of Diet Drugs which Interneuron and Wyeth Defendants knew or should have known about.

94. Interneuron and Wyeth Defendants failed to conduct sufficient and adequate post-marketing surveillance as to the ingestion of Diet Drugs and resultant adverse events and side effects to both properly determine and quantify the risks and severity of serious side effects and take reasonable and necessary remedial action to protect the public, including Plaintiffs, from injuries being suffered by Diet Drug users which Interneuron and Wyeth Defendants knew or should have known about.

95. Defendants failed to properly and adequately warn Plaintiffs, both directly and by and through Plaintiffs' prescribing physicians, of the dangers associated with Redux such that Plaintiffs' prescribing physicians did not have available to them the body of knowledge that an adequate warning from Interneuron would have communicated to Plaintiffs' prescribing physicians.

96. As a result of Defendants' acts and omissions and other tortious conduct more fully detailed and alleged herein, Plaintiffs have sustained significant heart valve regurgitation and resultant injuries.

97. Interneuron and Wyeth Defendants undertook a course of action and marketing strategy which included advertising and promotional campaigns to aggressively promote and sell the subject drugs.

98. The product warnings in effect during the time the Diet Drugs were prescribed were non-existent or inadequate as to the need to alert prescribing physicians and consumer patients of the actual adverse health risks associated with these drugs, which risks were then known (or should have been known) to the Interneuron and Wyeth Defendants. Potential users were not

informed about the products and the serious health effects which Interneuron and Wyeth Defendants knew or should have known could result from the use of the subject drugs.

99. Wyeth Defendants and Interneuron, through their misrepresentations and omissions, created the impression and conveyed to Plaintiffs and others on whom Plaintiffs would rely, that the use of the Diet Drugs alone or in combination with phentermine was safe and had fewer adverse health and side effects than were actually associated with the Diet Drugs.

100. Interneuron and Wyeth Defendants undertook a promotional campaign that included the funding of and/or placement of numerous articles in scientific, medical and general interest magazines extolling the virtues of the Diet Drugs in order to induce widespread use of the products.

101. Interneuron and Wyeth Defendants actively encouraged, or failed to effectively discourage, the widespread prescribing of the Diet Drugs to patients that were not clinically obese.

102. Interneuron and Wyeth Defendants downplayed and understated the health hazards and risks associated with the Diet Drugs.

103. Interneuron and Wyeth Defendants failed to reveal relevant information to doctors and potential Diet Drug users including Plaintiffs and their physicians regarding the safety of the Diet Drugs.

104. Interneuron and Wyeth Defendants' through their product inserts and other documents, misrepresented a number of facts regarding the Diet Drugs, including the following:

a) The presence of adequate testing of the Diet Drugs;
b) Diet Drugs' efficacy including but not limited to the severity, frequency and discomfort of side effects and adverse health effects caused by the drugs;
c) The relative risks associated with the Diet Drugs including the prevalence of pulmonary hypertension; and

d) The relative risks associated with the Diet Drugs including the prevalence of VHD.

105. After learning of the extreme dangers associated with the Diet Drugs, Defendants did not adequately or appropriately provide information about the Diet Drugs or other relevant information to physicians in the United States, including Plaintiffs' physicians.

106. At all times relevant hereto, the Defendants' labeling on the Diet Drugs were totally inadequate to alert Plaintiffs, prescribing physicians and others of PH, VHD and/or secondary pulmonary hypertension and other dangers and risks associated with Diet Drug usage. As a result, physicians have over-prescribed the Diet Drugs to patients who were under-informed regarding the risk of secondary pulmonary hypertension or VHD associated with the drugs.

107. At all times relevant to this cause, Interneuron and Wyeth Defendants also knew or should have known of many other studies, regulatory actions and concerns, incidences of injury and/or death, concerns about the subject drugs, safety among scientists, researchers, regulators and other knowledgeable professionals, the dangers of drug combinations, meetings among pharmaceutical industry officers, executives or employees (including Defendants), internal memos and reports of health concerns regarding the subject drugs, the lack of sufficient safety studies before and during marketing of the subject drugs, the contents of Defendants' own files, plans and reports, the danger of the off-label use of medications, safety concerns about the drugs which could block or change FDA approval, regulatory actions, reports of injury and concerns about the subject drugs in Europe, case reports of pulmonary hypertension, regulatory efforts to make changes in the warning and labels required on these products and the plans and actions of Defendants to fight such changes, statements by medical professionals regarding safety concerns for the subject drugs, and adverse effects reported therefrom, the failure of Defendants to report

incidences of PH resulting from the use of the subject drugs to regulators and health care professionals, the identification of groups most at risk of injury, and many other material facts regarding the Diet Drugs which would have shown the danger and adverse health effect of using the subject drugs, but did not inform Plaintiffs, the public at large, or Plaintiffs' physicians of these material facts and risks.

108. Defendants, having undertaken the manufacture, sale, marketing, distribution and promotion of the diet drugs described herein owed a duty to provide Plaintiffs, physicians, state regulators and others upon whom it was known, or should have known, by Defendants that Plaintiffs would rely, accurate and complete information regarding the subject drug products.

109. Interneuron and Wyeth Defendants indicated to Plaintiffs, Plaintiffs' physicians, regulators and others upon whom it was known, or should have been known that each Plaintiff would rely, that the Diet Drugs were safe and effective, that the benefits of taking the subject drugs outweighed any risks and provided inaccurate safety and effectiveness information regarding its products including but not limited to the propensity to cause serious physical harm. The continuous and ongoing course of action started as early as 1993, if not earlier, and continued through repeated acts and non-disclosure every year since then, in the State of Massachusetts and in those States in which the Plaintiffs resided, were prescribed and ingested the Diet Drugs, throughout the United States, and elsewhere.

110. Interneuron's and Wyeth Defendants' fraudulent misrepresentations took the form of, among other forms, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information

regarding the products while having a duty to disclose to Plaintiffs and others such information, and elaborate marketing, promotional, and advertising activities.

111. The Diet Drugs were in fact unsafe, and the use of the Diet Drugs posed an unreasonable risk of injury and death that outweighed the purported benefits of their use, such that injury was in fact caused to Plaintiffs and others.

112. Defendants, individually and jointly, failed to adequately warn Plaintiffs and those whom they knew Plaintiffs would rely of the hazards associated with the use of the Diet Drugs and failed to provide this knowledge from Plaintiffs and others. As a result of this failure to warn, Plaintiffs were caused to suffer injuries and damages.

113. The Diet Drugs were defective and unreasonably dangerous when they left the possession of Defendants in that, among other ways:

a. the Diet Drugs caused injury to the user far beyond any warned, noticed, expected or reasonable side effect or adverse reaction and when placed in the stream of commerce they contained unreasonably dangerous defects subjecting Plaintiffs to risks from expected or known usage, including bodily injury and death, which exceeded the benefits of the subject drugs;
b. when placed in the stream of commerce the Diet Drugs were defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with obesity and weight loss;
c. the Diet Drugs contained insufficient and/or ineffective warnings to alert consumers and users to the risks of injury and death by VHD and PH;
d. the Diet Drugs were insufficiently tested;
e. there were insufficient instructions on the proper use of the Diet Drugs;
f. there were inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the significant risks previously described, Defendants failed to provide adequate warnings to users and consumers, and/or their physicians, and continued to promote the sale and use of the subject drugs;
g. the Diet Drugs had not been materially altered or modified prior to the use of said drugs by Plaintiff; and
h. Defendants were in the business of distributing and selling the Diet Drugs which make the basis of this lawsuit.

114. Defendants assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold these products in a defective condition that was unreasonably dangerous to the user or ultimate consumer of this product. Each product was expected to and did reach the user and consumer Plaintiffs without substantial change in the condition at which it was sold.

115. As a direct and legal result of the defective condition of the Diet Drugs, Plaintiffs sustained and will continue to sustain serious and permanent injuries, physical pain and suffering, impairment, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life past and future; undergoing medical monitoring; loss of earnings and loss of the ability to earn money in the past and the future; expense of hospitalization, medical and nursing care and treatment and medical monitoring in the past and in the future; and fear and mental anguish concerning future medical problems associated with their injuries.

116. Defendants, Interneuron and Wyeth Defendants, employed, contracted, associated or otherwise engaged pharmaceutical sales persons, area account mangers, district managers, area development managers, area business directors and other representatives ("sales representatives") in furtherance of marketing, promoting, selling and/or distributing the Diet Drugs through the United States. Interneuron and Wyeth Defendants, by and through these sales representatives, provided inaccurate information or failed to provide information relating to the dangers associated with the Diet Drugs, to the consuming public, including Plaintiffs and Plaintiffs' prescribing physicians. During the course of their employment or other engagement with Interneuron and Wyeth Defendants, the sales representatives undertook the following both within the scope of their employment and at the instruction and/or direction of Interneuron and Wyeth Defendants: failed to convey adequate warnings to Plaintiffs through their prescribing

physicians; negligently distributed, marketed, advertised and/or promoted the Diet Drugs; made negligent misrepresentations regarding the safety and efficacy of the Diet Drugs; negligently failed to provide sufficient instructions to Plaintiffs and/or their prescribing physicians regarding the use of said drugs; made misrepresentations to physicians and staff, with the intent that these statements be relied upon to the detriment of patients, including Plaintiffs, including but not limited to: that the Diet Drugs were safe and effective when used as directed, and that the Diet Drugs were effective for long term weight loss. Moreover, Interneuron and Wyeth Defendants, by and through their sales representatives did not relay the true risk of serious cardiovascular and life threatening diseases such as VHD and PH.. Upon information and belief, these sales representative, armed with Plaintiffs' doctors' profile consisting of personal biographical information and periodic reports on prescribing habits, specifically discussed the importance of co-promotion of the Diet Drugs within the Interneuron and Wyeth Defendant network and with other companies and, in a coordinated fashion, implemented those discussions and agreements by bombarding prescribing physicians, including Plaintiffs' physicians, with misleading information about the Diet Drugs. As a result of the tortious actions described herein by Defendants, Interneuron's and Wyeth Defendants' sales representative agents, Interneuron and Wyeth Defendants are liable to Plaintiffs in strict products liability, negligence, fraudulent misrepresentation, fraudulent concealment, and unfair and deceptive trade practices, as well as those other actions pled in this complaint.

117. Plaintiffs were prescribed the Diet Drugs for weight loss. Plaintiffs received no warnings or statements regarding adverse effects of Diet Drug use which would warn Plaintiffs against the use of such Diet Drugs or that such Diet Drugs could cause VHD and associated injuries suffered by Plaintiffs.

COUNT I
STRICT PRODUCT LIABILITY
DEFECTIVE DESIGN

118. Plaintiffs adopt by reference all of the allegations above, each inclusive, as though fully set forth herein.

119. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the Diet Drugs that were defective and unreasonably dangerous to consumers, including Plaintiffs.

120. At all times material hereto, the Diet Drugs which were researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiffs, without substantial change in the condition in which they were sold.

121. At all times material hereto, the Diet Drugs were in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Diet Drugs contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of the drug;
b. When placed in the stream of commerce, Diet Drugs were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with obesity and/or weight loss;
c. Diet Drugs were insufficiently tested;
d. The intended use of the drugs caused harmful side effects which outweighed any potential utility; and
e. Diet Drugs were not safe for its intended use as a weight loss drug.